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HYFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known		
Application Number	09/931,506	
Filing Date	August 16, 2001	
First Named Inventor	Shannon MITCHELL	
Art Unit	1636	
Examiner Name	D. Sullivan	
Attorney Docket Number	000250.00025	

-	C).	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan
Examiner Initials *	Cite No. ¹	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages of Relevant Figures Appear
DS		US-2002/016000 A1	10/31/2002	Niklason et al.	424/145.1
i		US- 2003/0235562	12/25/2003	Niklason et al.	424 193 21
_		US- D323,895	02/11/1992	Protzmann	024/216
		US- 5,364,756	11/15/1994	Livesey et al.	435/2
		US- 5,622,867	04/22/1997	Livesey et al.	436/18
		US- 5,632,778	05/27/1997	Goldstein	424/423
DE		US- 5,780,295	07/14/1998	Livesey et al.	435/307.1
		US-			100/100

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0:1-	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant	
No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T [©]
	WO 97/08295	03/06/1997	Livesey etal		
	Cite No.1	Cite No.¹ Country Code³ - Number⁴ - Kind Code⁵ (if known)	Cite No.¹ Country Code³ - Number⁴ - Kind Code⁵ (if known) Publication Date MM-DD-YYYY	Cite No.¹ Country Code³ - Number⁴ - Kind Code⁵ (if known) Publication Date MM-DD-YYYY Applicant of Cited Document	Cite No.¹ Country Code³ - Number⁴ - Kind Code⁵ (if known) Country Code³ - Number⁴ - Kind Code⁵ (if known) Country Code³ - Number⁴ - Kind Code⁵ (if known) Name of Patentee or Applicant of Cited Document Applicant of Cited Document Publication Date MM-DD-YYYY MM-DD-YYYY Name of Patentee or Applicant of Cited Document Passages or Relevant Figures Appear

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
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R		ALLISON, S. Dean et al., "Effects of Drying Methods and Additives on Structure and Function of Actin: Mechanisms of Dehydration-Induced Damage and Its Inhibition," <i>Archives of Biochemistry and Biophysics</i> (October 1, 1998), pp. 171-181, Vol. 358, No. 1	
1		BEATTIE, Gillian M. et al., "Trehalose: A Cryoprotectant That Enhances Recovery and Preserves Function of Human Pancreatic Islets After Long-Term Storage," <i>Diabetes</i> , (March 1997), pp. 519-523, Vol. 46	
		ELMORE, James R. et al., "Cryopreservation affects endothelial and smooth muscle function of canine autogenous saphenous vein grafts," <i>J. of Vasculer Surgery</i> , (May 1991), pp. 584-592, Vol. 13, No. 5	
		FERBER, Dan., "Law-Grown Organs Begin To Take Shape," Science, (April 16, 1999), pp. 422-425, Vol. 284	
08		HILES, M.C., et al., "Mechanical properties of xenogeneic small-intestinal submucosal when used as an aortic graft in the dog," <i>J. Biomedical Materials Research</i> , (1995), pp. 883-891, Vol. 29	

Examiner Signature	Date S/12 /C4	
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K.	110.	HUYNH, Tam et al., "Remodeling of an acellular collagen graft into a physiologically responsive neovessel," Nature Biotechnology, (November 1999), pp. 1083-1086, Vol. 17	
nS		NiKLASON, L.E., *Replacement Arteries Made to Order,* Science, (November 19, 1999), pp. 1493-1494, Vol. 286	
08		RICH, S.J. and ARMITAGE, W.J., "Propane-1,2-diol as a Potential Component of a Vitrification Solution for Comeas," Cryobiology, (1990) pp. 42-54, Vol. 27	
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Signature Considered S/12/09	Signature 1005 000	Date Considered	8/12/04
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